

This Listing of Claims will replace all prior versions, and listings, of claims in the application:

LISTING OF CLAIMS

1 (currently amended): A lyophilized composition of TFPI or ala-TFPI ~~TFPI-variant~~ comprising (1) TFPI or ala-TFPI ~~TFPI-variant~~ and (2) a carbohydrate or amino acid glass forming agent, wherein the lyophilized composition has about 45% or greater aggregation stability.

2-3 (canceled)

4 (original): The lyophilized composition of claim 1 wherein the glass forming agent is selected from the group consisting of a monosaccharide, a disaccharide, a trisaccharide, a naturally occurring amino acid, and combinations thereof.

5 (original): The lyophilized composition of claim 1 which has an aggregation stability in a range selected from the group consisting of aggregation stabilities of about 45% or greater to about 95% or greater, about 70% or greater to about 95% or greater, and about 85 or greater to about 96% or greater.

6 (original): The lyophilized composition of claim 1 which has an aggregation stability in a range of about 45% or greater to about 96% or greater.

7 (currently amended): A lyophilized composition of TFPI or ala-TFPI ~~TFPI-variant~~, wherein before lyophilization the TFPI or ala-TFPI ~~TFPI-variant~~ is present in an aqueous

formulation comprising a carbohydrate or amino acid glass forming agent, wherein the aqueous formulation has a pH of about 4 to about 8.

8 (original): The composition of claim 7 wherein the aqueous formulation comprises about 50 mM to about 600 mM of the glass forming agent.

9 (original): The composition of claim 7 wherein the aqueous formulation further comprises about 5 mM to about 600 mM of a buffer.

10 (original): The composition of claim 9 wherein the buffer is selected from the group consisting of phosphate, succinate, glutamate, imidazole, citrate, histidine, glycine, arginine, and combinations thereof.

11 (original): The composition of claim 7 wherein the pH of the aqueous formulation is about 5.5 to about 6.5.

12 (currently amended): The composition of claim 7 wherein the aqueous formulation comprises a concentration of TFPI or ala-TFPI ~~TFPI-variant~~ selected from the group of concentrations consisting of:

- no more than about 10 mg/ml of the TFPI or ala-TFPI ~~TFPI-variant~~;
- no more than about 1 mg/ml of the TFPI or ala-TFPI ~~TFPI-variant~~; and
- no more than about 0.2 mg/ml of the TFPI or ala-TFPI ~~TFPI-variant~~.

13 (original): The composition of claim 7 wherein the aqueous formulation is selected from the group of formulations consisting of:

- about 300 mM arginine and about 20 mM sodium citrate, with a pH of about 5.5;
- about 3% (w/v) arginine and about 10 mM sodium citrate, with a pH of about 6;
- about 2% (w/v) lysine and about 10 mM sodium citrate, with a pH of about 6;
- about 8.5% (w/v) sucrose, about 0.1% (w/v) polyphosphate, and about 10 mM sodium citrate, with a pH of about 6;
- about 8.5% (w/v) sucrose and about 10 mM histidine, with a pH of about 6; and
- about 8.5% (w/v) sucrose and about 10 mM imidazole, with a pH of about 6.5.

14 (original): The composition of claim 7 wherein the aqueous formulation further comprises a crystal forming agent.

15 (original): The composition of claim 14 wherein the crystal forming agent is selected from the group consisting of mannitol, alanine, glycine, NaCl, and combinations thereof.

16 (original): The composition of claim 14 wherein the aqueous formulation comprises about 0.5% (w/v) to about 16% (w/v) of the crystal forming agent.

17 (original): The composition of claim 14 wherein the aqueous formulation is selected from the group of formulations consisting of:

about 3% (w/v) arginine, about 4% (w/v) mannitol, and about 10 mM sodium citrate, with a pH of about 6;

about 3% (w/v) arginine, about 2% (w/v) glycine, and about 10 mM sodium citrate, with a pH of about 6;

about 3% (w/v) arginine, about 4% (w/v) mannitol, and about 10 mM sodium citrate, with a pH of about 6;

about 1% (w/v) sucrose, about 4% (w/v) mannitol, and about 10 mM L-histidine, with a pH of about 6;

about 1% (w/v) sucrose, about 2% (w/v) glycine, and about 10 mM histidine, with a pH of about 6;

about 1% (w/v) sucrose, about 4% (w/v) mannitol, and about 10 mM imidazole, with a pH of about 6.5; and

about 1% (w/v) sucrose, about 2% (w/v) glycine, and about 10 mM imidazole, with a pH of about 6.5.

18 (currently amended): A lyophilized composition of TFPI or ala-TFPI ~~TFPI-variant~~ comprising (1) TFPI or ala-TFPI ~~TFPI-variant~~ and (2) a citrate buffer, wherein the lyophilized composition has about 45% or greater aggregation stability.

19 (original): The lyophilized composition of claim 18 which has an aggregation stability in a range of about 45% or greater to about 96% or greater.

20 (currently amended): A lyophilized composition of TFPI or ala-TFPI ~~TFPI-variant~~ comprising (1) TFPI or ala-TFPI ~~TFPI-variant~~, (2) sulfate, and (3) a phosphate buffer, wherein the lyophilized composition has about 45% or greater aggregation stability.

21 (original): The lyophilized composition of claim 20 which has an aggregation stability in a range of about 45% or greater to about 96% or greater.